U.S. Environmental Protection Agency
Office of Research and Development

BOARD OF SCIENTIFIC COUNSELORS EXECUTIVE COMMITTEE MEETING

Washington, DC
January 22-23, 2004

Thursday, January 22, 2004

Welcome, Introductions, and Overview

Dr. Jerry Schnoor (University of Iowa), Chair of the Board of Scientific Counselors (BOSC), called the meeting to order at 8:45 a.m., and welcomed the members to the January meeting. He introduced the new Designated Federal Officer (DFO), Ms. Lorelei Kowalski, as well as the new member of the BOSC, Dr. George Lambert, who is the liaison from EPA's Science Advisory Board (SAB). (Dr. Lambert's biographical sketch was distributed at the meeting.) Dr. Schnoor then asked the members and visitors to introduce themselves. Following the introductions, he quickly reviewed the agenda and asked if there were any comments. Ms. Kowalski noted that there is some time included for public comment at the end of the day, but no written or oral comments had been received from the public in response to the public notice of the meeting, and no one had requested to speak during the public comment period.

Ms. Kowalski gave a brief description of her background and reported that the BOSC Web Site has been moved so that her office can maintain the site. The new URL for the BOSC Web Site is http://www.epa.gov/osp/bosc. She noted that there is a link on the old site directing users to the new site. Ms. Kowalski commented that she is the new point of contact for all BOSC activities.

Dr. Schnoor said that most of the agenda focused on organizing the four new Subcommittees to review three Multi-Year Plans (MYPs)—Mercury, Global Change, and Endocrine Disruptors—and the computational toxicology plan (which is not yet an MYP). For each Subcommittee, the Board will discuss the additional expertise required, a schedule for Subcommittee meetings, and the charge for the review. Dr. Schnoor postponed approval of the September 2003 BOSC meeting minutes to Friday morning, and asked the members to review the minutes that evening.

Remarks from the AA/ORD

Dr. Paul Gilman, Assistant Administrator for Research and Development (AA/ORD), thanked the Board members for serving on the BOSC. He noted that EPA is working its way through the list of nominees for the vacant positions on the Board and hopes to have some new members approved before the next meeting. Dr. Gilman announced his intention to nominate Dr. Jim Johnson (Howard University) as the next Chair of the BOSC to replace Dr. Schnoor, whose term on the BOSC expires in May 2004.

Dr. Gilman mentioned that EPA offered a "buyout" last year to encourage senior and administrative staff to retire, and about 60 staff in ORD retired as a result of this incentive, including two senior staff (the Acting Director and Associate Director for Ecology) at the National Risk Management Research Laboratory (NRMRL). Dr. Gilman noted that these retirements mean that there will be even more staff acting in management positions within ORD. He said that Henry Longest, the Deputy Assistant Administrator for Management in ORD, also will be retiring, but he has agreed to remain at ORD for 1

year to help fill the many vacant positions. Dr. Gilman asked for input from the BOSC regarding attracting and recruiting the best individuals for these vacancies. He mentioned the possibility of term-appointments, such as those used by the National Institutes of Health (NIH), noting that such mechanisms will be essential for EPA given the large number of high-level openings that must be filled. Dr. Gilman said that he is working diligently to get that authority in place and he is hopeful, but not optimistic, that it will be approved. He referred to the difficulties that the National Aeronautics and Space Administration (NASA) experienced in getting such hiring authority, and NASA was granted only 10 slots (compared to the 150 positions at the National Institute of Environmental Health Sciences [NIEHS]). In response to Dr. Johnson's question concerning other options, Dr. Gilman replied that EPA is using the post-doc program to fill a number of vacant slots.

Dr. Gilman reported that EPA recently launched its P3 award—a student design competition that will provide grants to teams of college students to research, develop, and design sustainable solutions to environmental challenges. The teams will be invited to bring their designs to Washington, DC, to compete for the P3 Award. The National Academies will convene a panel to judge the competition, and winners of the P3 Award will be eligible for additional funds from EPA to match contributions from industry or non-governmental organizations (NGOs) to help further develop the design, implement the project in the field, and move the design to the marketplace. Dr. Gilman noted that P3 applications should be submitted by April 2004 (see http://epa.gov/ncer/p3).

Dr. Gilman said EPA issued guidelines for peer review and the Agency is one of the leaders in the use of peer review. In 2002, approximately 850 work products were identified for peer review. This is an extraordinary number, far in excess of most agencies. He is proud of EPA's impressive record of peer review and believes that it should be better publicized.

The EPA Science Inventory was released to the public on November 17, 2003, making EPA's quality science available to individuals and organizations outside the Agency. The Science Inventory is a searchable, Agency-wide database of more than 4,000 scientific and technical work products. Database records provide such information as project descriptions (abstracts), contacts for additional information, and electronic links to final reports and related research.

EPA soon will be releasing guidance for all forms of modeling—how to develop a model, how to verify its performance, and how it should be peer reviewed. The guidance will be the best practice for Agency staff as well as those outside EPA. It will be subjected to peer review as well as a longer review by the National Academy of Sciences (NAS). The guidance includes 90 of the Agency's most frequently used models and databases, and what has been done with those models. It also addresses proprietary models and steps that modelers can take to make these appropriately transparent. Dr. Gilman noted that several owners of proprietary models are included in EPA's knowledge base and the owners have complied with EPA's guidance. Dr. Rogene Henderson (Lovelace Respiratory Research Institute) asked if the Board members could receive copies of the guidance, and Dr. Gilman replied that it is expected to be released next Wednesday, January 28, 2004.

On December 31, 2003, ORD unveiled a new Web site, the Environmental Technology Opportunities Portal (ETOP), that will provide one-stop-shopping for assistance in funding development of new environmental technologies. ETOP links users to programs that foster development and commercialization of new environmental technologies and information on existing environmental technologies.

Dr. Gilman reported that he has been asked to chair a panel that will revisit issues associated with the cleanup of apartments located near the World Trade Center (WTC), following its collapse. He reminded the BOSC of the Inspector General's report that questioned some of EPA's decisions. In response, EPA

is convening a panel that includes Agency staff, as well as representatives from other agencies and New York City. Apartments will be sampled to determine if the cleanup efforts have been effective. Dr. Gilman noted that this is a significant public relations challenge.

Dr. Gilman identified some of the themes of the FY 2005 budget. These themes include: better coordination of technology programs, outcomes related research to better understand the outcomes of the Agency's research and regulatory activities (the initial focus will be health outcomes), and high-performance computing and intellectual and computational grids. Dr. Gilman mentioned that upgrading the Agency's high-performance computing capabilities will help EPA connect with other agencies to share large data sets and improve model performance. One example of what will be possible with such data sharing is the system to be piloted by EPA and the National Oceanic and Atmospheric Administration (NOAA) to forecast ozone and eventually particulate matter. Dr. William Farland, the Deputy Assistant Administrator for Science in ORD, pointed out that the next BOSC meeting will be held in Research Triangle Park, NC, and the Board members will have an opportunity to see a demonstration of the new high-performance computing capability. Dr. Gilman said that EPA is working with NOAA and the Department of Energy to initiate grid computing that will improve the precision of models for urban landscapes. Lower Manhattan has been simulated in a wind tunnel model at EPA's facilities in RTP, in an effort to create tools that better predict exposure. EPA also is working with Rutgers to model exposure associated with the collapse of the WTC.

Dr. Gilman mentioned two topics that the BOSC may want to discuss at future meetings: (1) the second effort on understanding coastal health, and (2) the biotechnology program. Dr. Gilman said that the Environmental Monitoring and Assessment Program (EMAP) provided the first data on the health of coastal areas. This is the Agency's second opportunity to look at large ecosystems in a scientifically valid way and draw conclusions about their health. He noted that this is a followup to the Coastal Conditions Report. The second topic—the biotechnology program—was introduced to the BOSC at a previous meeting. The program is beginning to generate data and the Board may want to provide ORD some feedback on the data. Dr. Gilman pointed out that EPA is trying to figure out how to do more with less, so it may be necessary to examine how to change the flow of some Agency programs; ORD may need quick turnaround input from the BOSC on some of these issues. Dr. Johnson asked if these changes would be in line with the MYPs, and Dr. Gilman replied that some would be but not all ORD activities are included in MYPs.

Given that the focus of this meeting is the MYPs, Dr. Schnoor asked Dr. Gilman to provide an update on the status of the National Program Directors (NPD). Dr. Gilman reported that the Agency will be moving to a different model for managing its research programs. ORD has created nine NPD positions to manage implementation of the MYPs, and unlike previous National Program Managers, the NPDs will have the budget authority to manage the programs. ORD is in the process of rethinking the roles of the Laboratory/Center Directors and how decisions are made within the organization. The NPDs will build their programs across the Laboratories and Centers. ORD has moved to this new model to enhance coordination across the Laboratories and Centers. Job descriptions for the NPD positions have been posted on the Web.

Dr. Schnoor said that EPA has benefitted from Dr. Gilman serving as both the AA/ORD and the EPA Science Advisor, and asked if that dual position will be permanent. Dr. Gilman responded that it has not been formalized. He reported that a major role of the Office of the Science Advisor is to work with the Regional Offices to bolster the science used in the Regions for risk assessments, Records of Decision, and other actions. Another activity commissioned by the Science Advisor is the review of the state of risk assessment staff paper. One finding is that EPA need to rely more on probability-based tools for risk assessments. EPA now needs to train staff and take other measures to promote more use of these tools. Dr. Gilman indicated that he will share the results of the review with the BOSC in the near future. With

regard to computational toxicology, Dr. Gilman has met with a number of companies to discuss how these groups can demonstrate the power of these technologies to the regulators.

At the time of the September BOSC meeting, Michael Leavitt's approval hearings were ongoing. Since then, Mr. Leavitt has been confirmed and actively engaged. Mr. Leavitt was at EPA only 9 days when he made his first trip to RTP. When in RTP, Mr. Leavitt asked about grid computing, which gave the Laboratory staff an opportunity to describe their efforts and the collaborations with other agencies and states to move toward an environmental net. Dr. Gilman said he and others at ORD have briefed the new Administrator on some tough issues, and Mr. Leavitt quickly dives into the deep questions. For example, he has asked Dr. Farland and Dr. Peter Preuss (ORD/NCEA) to prepare a list of the 10 questions that should be asked of someone briefing him on a risk assessment.

Dr. Ann Bostrom (Georgia Institute of Technology) asked if ORD has taken efforts to communicate its research in grid computing. Dr. Gilman replied that not much has been done yet; EPA did issue a press release to explain grid computing and the purpose of the Agency's research. He noted that ORD will revisit the communications issue in the future.

Dr. George Lambert (UMDNJ-Robert Wood Johnson Medical School) asked if there has been any interaction between EPA and NASA on using satellites for environmental monitoring. He noted that NOAA organized a meeting that brought together user groups from around the world to discuss the possibility of forming a worldwide observation network that could share data. Dr. Gilman said that EPA was very involved in that meeting as well as the subsequent meeting in Italy. The next meeting of this group will be held in Japan. Dr. Gilman indicated that EPA is trying to get NASA to focus on user needs and the Agency is actively involved in driving the U.S. position on these networks. Administrator Leavitt said that he wants EPA to be a leader on this issue, so there is management support for the Agency's continued involvement in the collaborative effort.

Multi-Year Plan Reviews

Dr. Farland stated that the draft charges for the MYP reviews are included in the meeting notebook. He asked the BOSC members to review the three charges and comment on them during the respective discussions. He noted that Dr. Gilman would prefer a prospective, rather than retrospective, review of the Mercury MYP. The review should examine how well ORD is articulating the science, communicating the science, and defining its niche. ORD needs input that will improve the next generation of this MYP. The draft charge for the Mercury MYP focuses on whether ORD is addressing the relevant questions.

The charges for the Global Change and Endocrine Disruptors MYPs are similar, but different, from the charge for the Mercury MYP. Dr. Farland noted that the charge for the Computational Toxicology Subcommittee will be very different from these charges. Dr. Schnoor reminded the BOSC that the charge for the Mercury MYP was approved by the Board and the members agreed to use it as a template for the other reviews. The Subcommittees Chairs, however, thought that the charges needed to be more consistent. He noted that this is the Board's opportunity to revise these charges. Dr. Bostrom asked if there could be more consistency in the core elements of the charges. For example, the Global Change charge could be more consistent with the key issues covered in the Mercury charge. Also, the integration issue mentioned in the Climate Change charge should be included in the Mercury charge. Dr. Schnoor agreed and asked Drs. Bostrom, Johnson, and Henderson to work together to reword the charges and to make them more parallel. He asked that this task be completed by Friday morning. Dr. George Daston (P&G) agreed to provide them with his rewording suggestions.

Dr. Henderson asked if there are research strategies associated with these three MYPs, as there was with the Air Toxics MYP. She noted that the strategy provided a good overview of the research program and

the MYP provided the specifics of the research to be conducted. Dr. Farland replied that the BOSC will be provided both documents for review when they are available. He pointed out that there will not be research strategies for all of the MYPs. Dr. Anna Harding (Oregon State University) asked if the Subcommittees should review other materials and if ORD would provide the Board copies of other documents (e.g., the World Health Organization's report on endocrine disrupting chemicals [EDCs]). Dr. Farland replied that these are the Board's reviews and other documents can be provided to the Subcommittees on request. Dr. Daston said that he thought it would be easier to read the strategy and MYP without having to review the source documents. Dr. Elaine Dorward-King (Rio Tinto Borax) pointed out that additional expertise will be needed on the Subcommittees. She asked if the NPDs will be available to the BOSC, and Dr. Farland replied that they will make presentations and respond to the Subcommittee's questions as needed. Dr. Daston commented that these reviews should examine whether the plans are in alignment with the Agency's overall mission, the research serves to achieve a particular goal, the plan provides for sound science, and the research is feasible and not redundant with that of other organizations. Dr. Kevin Teichman (ORD/OSP) added that the review should determine if there is a communications plan in place to transfer results to the user community. Dr. Farland stated that the Subcommittees also should look at issues of evaluation. Are there research opportunities that will provide tools for measuring success? Dr. Schnoor indicated that he had the BOSC's letter review of measures of success if the Board members would like to review it.

Dr. Bostrom commented that the Global Change MYP includes statements about certain accomplishments. Perhaps the plan should include a list of accomplishments. Dr. Farland agreed that this issue should be discussed. He noted that the original drafts of the MYPs did not contain descriptions of accomplishments; these were added in the last iteration. Dr. Schnoor thought it was important for the plans to indicate the starting point and what has been accomplished.

Mercury MYP Subcommittee Discussion

Dr. Herb Windom (Skidaway Institute of Oceanography) agreed to chair the Mercury Subcommittee, but he was unable to attend this meeting. Dr. Farland introduced Bill Stelz (ORD/NCER) and James Avery (ORD/OSP) who were very involved in preparing the Mercury MYP and strategic plan. Dr. Schnoor asked the Subcommittee members—Drs. Henderson and Johnson—to comment on the types of additional expertise needed for the review. Ms. Kowalski distributed a list of disciplinary expertise for the SAB database of members and consultants. She also provided lists of individuals resulting from searches of the SAB database for the areas of mercury, global change, global climate change, and atmospheric science. Ms. Kowalski noted that these individuals may not have the appropriate expertise; their inclusion on the list means that their resumes contained the search term. She noted that all of the individuals on the lists are Special Government Employees (SGEs), which makes it easier to process the paperwork required for BOSC Subcommittee membership. Dr. Elaine Francis (ORD/NCER), NPD for Endocrine Disruptors, said she can provide Ms. Kowalski with a list of terms to use when searching the database for appropriate experts for the Endocrine Disruptor MYP Subcommittee. Dr. Francis also mentioned that NCER's Peer Review Division has a database of peer reviewers that might be helpful in identifying additional experts. Dr. Henderson asked if it is possible to include government employees on the Subcommittees. Is that a lengthy and difficult process? Ms. Kowalski agreed to research this issue and get back to the Board with an answer.

Dr. Schnoor asked for comments on the Mercury charge. Dr. Bostrom suggested that the charge include something about the Annual Performance Measures (APMs) and Annual Performance Goals (APGs), similar to item 4 in the Global Change charge. Dr. Henderson commented that she liked items 2, 5, and 6 on the Global Change charge. It is important to determine if the MYP is consistent with the goals in the strategic plan. Dr. Schnoor asked if the charge should include an item on communication. Dr. Farland replied that the MYPs do not contain communication plans. He suggested a better question to ask would

be if the outputs identified in the plan lend themselves to good communication. Are the products/outcomes that will be communicated supportive of EPA's mission? Dr. Schnoor suggested adding the question: Is there a plan to communicate the results generated by the research in the MYP? He said that item 6 of the Global Change charge may be too specific for the MYP reviews. Dr. Farland explained that if the outputs of the MYP are literature citations or published papers, then the MYP does not include products/outputs that will effectively communicate the accomplishments. Mr. Stelz mentioned that NCER is synthesizing the accomplishments of the mercury STAR grants awarded in 1999. There are plans to do a series of these synthesis documents for various STAR grants to report the contribution of the program. The BOSC members agreed on two additions to the mercury charge—one focused on communications and the other on flexibility (similar to item 5 of the Global Change charge).

Dr. Johnson indicated his desire to "fast track" the Mercury MYP review, perhaps by having it reviewed by the BOSC Executive Committee. He thought it might be helpful to complete one review to develop a model for the subsequent reviews. Dr. Henderson did not agree that the Executive Committee should review the Mercury MYP; however, she did support the idea of a "fast track" review for mercury.

Dr. Henderson indicated that Dr. Windom has the required ecological expertise and possibly the aquatic fate and transport expertise, Dr. Johnson has the engineering expertise, and she has toxicology expertise. Additional expertise is needed in fate and transport and neurobehavioral toxicology. Dr. Daston suggested including an epidemiologist because epidemiological data are driving the regulations. Dr. Farland pointed out that the Mercury MYP does not focus on mercury health effects. EPA's mercury research efforts are focused on the control of emissions to the environment and whether local emissions or global emissions are of more concern with regard to an impact on the population. The Mercury MYP does not include health effects because there are a number of other agencies (Agency for Toxic Substances and Disease Registry [ATSDR], Centers for Disease Control and Prevention [CDC]) conducting that research. In addition, EPA's relevant expertise is control technology and fate and transport. Dr. Daston responded that the research will identify different control plans with different costs, but how much we are willing to pay will be based on the health effects, which are based on the reference dose. Therefore, the validity of the reference dose is a primary concern. Is the basis for setting the reference dose accurate? Dr. Farland stated that NAS found that the statistical approach used with the epidemiological data is a critical issue. There is little known about the interfaces of exposure. Dr. Michael Clegg (University of California–Riverside) asked why ORD had only eight full-time equivalents (FTEs) assigned to this program given the the large number of individuals with levels above the reference dose. Dr. Farland said that is an appropriate question for the BOSC to ask. The Subcommittees also may want to ask ORD what additional research would be conducted if the budget is increased. The MYP reviews should determine if the research is meaningful and building on the efforts of others.

Dr. Henderson asked if there is a limit on the number of Subcommittee members. Dr. Schnoor replied that there is no formal limit, but there have been no more than 6 members on previous BOSC Subcommittees. Dr. Farland concurred and stated that there is some concern about creating Subcommittees that are too large to work efficiently. Cost is another concern.

In reviewing the list provided by Ms. Kowalski, Dr. Dorward-King stated that either Gerald Keeler or Edo Pellizzari, both atmospheric fate and transport experts, would be a good addition to the Mercury MYP Subcommittee. Other names mentioned for consideration include: Michael Waalkes (NIEHS), Steve Lindberg (ORNL), Sue Schantz (University of Illinois), Joe Delphino (University of Florida), Debbie Cory-Slechta (University of Rochester), Mike Bolger (FDA), and Deborah Rice (Maine Department of Environmental Protection). Although other researchers at Rochester were mentioned, Dr. Farland pointed out that they were they primary authors of the EPA documents. He suggested doing another search of the SAB database, and Dr. Francis indicated that another source would be the National Research Council (NRC) peer review panel for the research strategy. Dr. Schnoor thought it best to

exclude members of the NRC panel, but it might be appropriate for one of them to present the panel's conclusions to the Subcommittee. Dr. Farland mentioned that Louise Ryan (Harvard School of Public Health) was on that panel. Dr. Windom asked Dr. Henderson to suggest Cindy Gilmore (The Academy of Natural Sciences) for consideration. Dr. Daston identified two epidemiologists, Kim Thompson and George Gray (Harvard School of Public Health), for consideration by the Subcommittee members. Dr. Henderson said that she will contact Drs. Johnson and Windom to discuss these names and to identify others. Dr. Lambert mentioned an upcoming neurotoxicology meeting and agreed to provide the list of speakers to Dr. Henderson. Dr. Schnoor asked the BOSC members to provide names of appropriate experts to Dr. Henderson by January 30. He also requested that Dr. Henderson send the names of potential Subcommittee members to Ms. Kowalski as soon as possible.

Dr. Schnoor mentioned that the Subcommittee meetings had to be advertised to the public 30 days in advance of the meeting. Dr. Henderson said she hopes to schedule the first Subcommittee meeting before the May BOSC meeting in RTP. Dr. Farland commented that ORD could use the BOSC's input on the Endocrine Disruptors and Global Change MYPs as soon as possible, because these programs will be reviewed by the Office of Management and Budget (OMB) in summer 2004.

Dr. Henderson mentioned that the Air Toxics MYP review by the SAB was very efficient. Each Subcommittee member was assigned a certain section of the MYP to present and lead the discussion. Dr. Henderson stated that ORD staff were responsible for presenting the strategic plan. In response to Dr. Harding's request, Dr. Henderson quickly reviewed the process used for review of the Air Toxics MYP. Each member of the Subcommittee led the discussion of a certain section of the MYP. The individual who led the discussion also was responsible for writing that section of the review report. A draft report was prepared within 1 month of the review meeting and it was revised and finalized via e-mail. Dr. Henderson thought this model worked very well. Dr. Schnoor suggested using this model for the BOSC reviews and a number of the members agreed.

Dr. Henderson said that she would like to hold the first Mercury MYP Subcommittee meeting by the end of March. She envisions a day-and-a-half meeting at which the ORD staff can respond to the self-study questions developed by the Subcommittee. Dr. Farland asked Dr. Henderson to consider if the Subcommittee wanted presentations from other agencies. If so, the invitations should be sent as soon as possible.

Mr. Stelz pointed out that the MYPs are dynamic documents and the priorities in the plans will change with time. He noted that the BOSC reviews will be helpful for preparing the next iteration of the plans. In response to Dr. Bostrom's question about meeting APMs and APGs, Dr. Farland replied that the MYP articulates where the work being done by other laboratories and agencies feeds into EPA's research program. For example, achievement of a particular APG may depend on research conducted by FDA. Dr. Bostrom said that if achievement of an APM or APG is contingent on the work of another agency, this should be clearly stated in the plan.

Computational Toxicology Subcommittee Discussion

Dr. Daston stated that EPA has developed a framework for computational toxicology research and conducted a workshop on this topic. The concept behind the strategy for computational toxicology is to take the most promising technologies and approaches and use them to improve, for example, predictions for risk assessments. Dr. Larry Reiter, Director of the National Health and Environmental Effects Research Laboratory (NHEERL), and Dr. Bob Kavlock (ORD/NHEERL) are here today to present some background on ORD's computational toxicology efforts and to describe the computational toxicology framework. Dr. Daston noted that ORD would like the Computational Toxicology Subcommittee to function more as an advisory committee to advise EPA as the program moves forward.

Dr. Reiter pointed out that computational toxicology is an ORD-wide program that cuts across all of the Laboratories and Centers. ORD is asking for input from the BOSC as it moves toward preparing a research plan for computational toxicology. He mentioned that the SAB reviewed the framework document and was very enthusiastic about it. ORD wants to use the framework as the departure point for engaging the BOSC Subcommittee. Dr. Reiter said that he would like to come back to the BOSC after the Board has looked at the framework document and discuss development of the research plan. There are many decisions that need to be made concerning EPA's focus and the BOSC can provide valuable input for these decisions. Dr. Reiter also would like the BOSC to review the research plan before it is finalized.

In FY 2002, Congress redirected funds to provide for non-animal alternative testing, and in FY2003, the effort continued, using EDCs as proof of concept. In July 2002, the Science Policy Council released an interim genomics policy (available at http://www.epa.gov/osp/spc/genomics.htm). With leadership from Dr. Gilman, ORD made a commitment to a strategic emphasis on computational toxicology, and the BOSC was briefed on this topic at the September 2002 meeting. A Genomics Task Force was created to develop a plan for moving this program forward. Dr. Reiter noted that the interim genomics policy encourages and supports continued genomics research as a powerful tool for understanding the molecular basis of toxicity and developing biomarkers of exposure, effects, and susceptibility.

The Computational Toxicology Framework was submitted to the SAB for review in September 2003. In reviewing the framework, the SAB was asked to examine the soundness of the organizing principles, determine if it addresses major issues of concern and key scientific uncertainties, suggest priorities and identify additional issues, and assess the feasibility of the proposed process. The SAB found that the document was well constructed, the strategy was sound and a good starting point for the program, and the proof-of-concept was a reasonable beginning. The SAB recommended that ORD engage the policy arms of the Agency in moving forward with the program, and make an effort to more clearly define the next steps.

Dr. Reiter pointed out that the framework is directed to the broader scientific community, extending way beyond what EPA has the resources to accomplish. The framework was introduced at a computational toxicology workshop that was held in September 2003, to bring together representatives of the broader scientific community to discuss how various agencies might work together to implement this research. Dr. Reiter noted that it is critical to view extramural scientific organizations as integral to the program. The workshop highlighted various approaches (e.g., diagnostic indicators, high throughput screening, toxicity pathway identification, metabonomics, and systems biology), as well as regulatory needs.

The FY 2004 budget continues expansion of the endocrine disruptors proof-of-concept, and the FY 2005 budget includes a partnership with the Office of Pesticide Programs (OPP) on anti-microbials. Dr. Reiter reported that ORD has begun to develop infrastructure to support this research. Affymetric stations have been established in RTP and Cincinnati, and a 600 Mhz wide bore NMR will be installed at the National Exposure Research Laboratory (NERL) in Athens, GA. NHEERL has purchased a Cyphergen proteomics station and a Luminex proteomics station, and has issued a contract for expression analysis.

Dr. Reiter indicated that ORD has been actively pursuing partnerships with other organizations. EPA signed a Memorandum of Understanding (MOU) on toxiocogenomics and systems biology with the CIIT Center for Health Research. EPA is working with the Department of Energy (DOE) Joint Genome Institute (JGI) to sequence information on ecologically relevant species. ORD also is developing collaborations with DOE's Pacific Northwest National Laboratory (PNNL) in the areas of systems biology, proteomics, and metabonomics, and with Sandia National Laboratory on NMR data signatures and microarrays. Discussions are underway for establishing an MOU with NIEHS, and for participating in a Committee on the Environment and Natural Resources (CENR) working group, as well as an Food

and Drug Administration (FDA) working group. Dr. Reiter mentioned that ORD also is developing partnerships with NGOs, including working with GeneLogic (proof of concept on predictive genomics), Affymetrix (proof of concept on endocrine disruptor screening and testing), and HARC (predictive toxicogenomics).

ORD also has funded a number of STAR grants to support the computational toxicology research program. In FY 2003, six projects on high throughput screening for EDCs were funded. Also in FY 2003, ORD issued a Request for Applications (RFA) on systems biology of HPG/T axis of small fish or rodents. ORD has $2.5 million of funding for these grants, and the closing date for the RFA was January 21, 2004. In FY 2004, ORD's budget includes $2.5 million for the Centers for Bioinformatics.

Dr. Reiter concluded his presentation by identifying the following next steps: (1) develop and implement a research plan, (2) issue STAR RFA on bioinformatics, (3) target strategic hires in ORD, (4) continue to develop partnerships, (5) organize small workshops across EPA, and (6) maintain a dialogue with the BOSC. Dr. Reiter emphasized that ORD has made a commitment to fund this program and he is very excited about the opportunities it could afford the Agency. It offers the potential for better prediction and prioritization and for reducing the uncertainties in quantitative risk assessments.

Dr. Kavlock stated that the overall goal of the computational toxicology research program is "to integrate modern computing and information technology with molecular biology to improve Agency prioritization of data requirements and risk assessment of chemicals." The ORD Technical Design Team was formed in late 2002, and it included representatives from the five ORD Laboratories/Centers. The charge to the team was to: (1) develop a framework for a computational toxicology research initiative, (2) plan and conduct a computational toxicology workshop, and (3) compile a bibliography for computational toxicology. Dr. Kavlock pointed out that development of a research strategy in computational toxicology is an APM in FY 2004. The Design Team has been replaced by the Implementation Team (CTISC), which is smaller than the Design Team, but still representative of the five Laboratories and Centers.

The overarching themes of the framework include: (1) a technology-based, hypothesis-driven effort to increase the soundness of risk assessment decisions within EPA; (2) building the capacity to prioritize, screen, and evaluate chemicals by enhancing the predictive understanding of toxicity pathways; and (3) success measured by ability to produce faster and more accurate risk assessments for less cost relative to traditional means and to classify chemicals by their potential to influence molecular and biochemical pathways of concern. The general objectives are to improve linkages in the source-to-outcome paradigm, provide predictive models for screening and testing, and enhance quantitative risk assessment.

Dr. Kavlock presented a diagram of the source-to-outcome continuum that depicts the risk assessment paradigm as a continuum of events leading from release in the environment to adverse effect. The diagram identified points along the continuum where a measurement or an observation can be made. ORD's research program focuses on learning more about the processes that lead from exposure to adverse outcomes to allow the Agency to perform better risk assessments. Dr. Kavlock identified the research needs for improving the linkages in the source-to-outcome paradigm. These research areas and needs include:

- ✧ Chemical Transformation and Metabolism—determine minimal concentrations at which biological events occur, identify biologically relevant chemical(s) in mixtures, identify crucial biotransformations in the environment, build libraries of relevant metabolic transformation pathways, develop high-quality data metabolic maps, and provide probability indices for substructural units.

- ✧ Exposure Indicators—develop a platform or sequence of approaches where "the earliest recognizable signatures of exposure" are identified for scores of different stressors, become user-friendly procedures, are demonstrated in case studies, and incorporated into the Agency, state, and regional studies that support EMAP and other programs.

- ✧ Dose Metrics—enhance dose models with specific data on stressor interactions with molecules initiating toxicity pathways, reduce uncertainty stemming from assumptions of homogeneous populations with genetic polymorphism data, and develop susceptibility indicators for input into exposure models.

- ✧ Characterization of Toxicity Pathways—identify discrete molecular initiating events, link adverse outcomes to molecular alterations, elucidate linkages across biological levels of organization, provide biological basis for cross-species extrapolation, and predict possible interactions for untested chemicals and mixtures.

- ✧ Metabonomics—elucidate changes in chemical-induced metabolic patterns for range of endogenous metabolites, generate NMR spectral profiles for chemicals, and build models to evaluate effect of novel chemicals on endogenous metabolites. The required equipment will be installed in the Athens laboratory in the next several months.

- ✧ Systems Biology—develop computational models that reconstruct a cell, organ, or organism's function from component parts; and allow validation and simulator experiments that build confidence in predictive ability of adverse effects. ORD is using the STAR program to support this research.

- ✧ Modeling Frameworks and Uncertainty Analysis—standardize format and interchange protocols for information generated by computer simulation, develop technology for linking required databases, and develop uncertainty analysis methods.

Dr. Kavlock also discussed the need to develop predictive models for hazard identification as the second objective of the program. The plan includes three areas where computational approaches are being considered or where such methods could have an impact: (1) quantitative structure-activity relationships (QSAR) and other computational approaches, (2) pollution prevention strategies, and (3) high throughput screening. ORD's current activities include conformational analysis, systematic expansion of models to apply to large chemical inventories, and metabolic simulation.

The third and final objective of the program is to apply computational toxicology research to enhance the Agency's current quantitative risk assessments and contribute to the development of new methods that are consistent across endpoints and species. This area involves validating and developing protocols, defining responses, and modifying uncertainty factors. Three potential applications of computational toxicology in quantitative risk assessment are dose-response assessments, cross-species extrapolations, and chemical mixtures.

In response to an FY 2002 Congressional mandate to explore alternatives to animal testing, ORD began a research effort to explore the use of emerging technologies and computational approaches to better prioritize chemicals for screening and testing. Because much is known about how EDCs interact with biological systems to cause adverse health, it was decided to focus the program on this class of chemicals and to conduct several proof-of-concept experiments to determine the feasibility of using computational toxicology approaches to meet an immediate Agency need. The use of QSAR models of receptor binding was proposed to help prioritize chemicals for screening. ORD is taking 70 chemicals that showed some evidence of receptor interaction and generating K_i values for each of them. This will provide an unbiased and unequivocal measure of receptor binding. Once these data are obtained, ORD will rederive the

QSAR models using the new training set and predictability will again be assessed. ORD also is studying thyroid gland functioning in ecologically relevant species by examining the integrating function of the vertebrate hypothalamic-pituitary axis in responding to the presence of EDCs. Given that thyroid function can be perturbed at different points in the thyroid pathway, research is being directed at developing a suite of endpoints that could ascertain which toxicity pathway is initiated by a specific chemical. Another area covered by ORD's research on toxicity pathways involves exploring the possibility that through the use of genomic and proteomic evaluations a single *in vivo* test for endocrine disruptor activity can be developed that will meet the essential requirements for an EDC screening assay. Taking advantage of the fact that there is a wealth of information available concerning the physiological regulation of the thyroid, adrenal, and gonadal axes by the hypothalamus and the pituitary glands, it may be possible to test empirically the extent to which changes in these endocrine systems are sensed and responded to by the central nervous system. ORD anticipates that the development of "genomic response profiles" following exposure to EDCs of known action will provide the means to identify the target pathways that lead to altered reproductive/thyroid/adrenal function.

Dr. Daston commented that using EDCs as a test case provides ORD the opportunity to bring a range of computational toxicology tools together. Dr. Kavlock mentioned that ORD is developing biochips for fathead minnow and *Xenopus*. Dr. Reiter added that the cooperative research and development agreement (CRADA) he mentioned in his presentation is to produce those biochips. Dr. Harding asked when ORD will be able to use what it has learned in the risk assessment process. Dr. Kavlock replied that there are many small steps that need to be taken first. ORD will be able to identify cell signals and have a better understanding of dose response before that happens. Response to low doses will be much more difficult to do, and Dr. Kavlock stated that ORD will not be doing low dose extrapolations in the near future, but there likely will be chemical-specific risk assessments that are added by comprehensive dose and time analysis of one or a few key genes in a toxicity pathway within the next few years. He noted that the pharmaceutial industry has invested billions of dollars in this research and they have yet to be able to fully tap its potential. Dr. Daston said that the pharmaceutical industry will soon be using it for hazard screening.

Dr. Bostrom asked if ORD has a systematic approach to uncertainty in this program. She explained that so much in the plan is presented as certain, when there are many uncertainties. Dr. Kavlock pointed out that ORD started with EDCs for which much is known about the pathways; when work starts on chemicals for which little is known about the pathways, there will be more uncertainties. Dr. Henderson asked about the variability and reliability of the chips. Dr. Daston replied that the chips are the single largest source of variability. It is critical to use chips from the same lot.

Dr. Schnoor asked about additional members for the Computational Toxicology Subcommittee, and Dr. Daston replied that he would like to add three to four members. Dr. Reiter suggested that Dr. Daston review the list of SAB consultants to identify the required experts. Dr. Daston agreed to review the list and provide the names of potential Subcommittee members to Ms. Kowalski as soon as possible.

EPA Science Inventory Demonstration

Paul Zielinski (ORD/OSP) reported that the EPA Science Inventory was made available to the public on November 17, 2003. Researchers at colleges, universities, state and local government, and industry, as well as students, attorneys, and others interested in EPA's science, now have access to the Agency's valuable tools. The Science Inventory provides another window for the world to see the science EPA uses to inform Agency decisions, and it highlights EPA's extensive peer review of its products. The inventory is searchable and it is updated continuously by EPA staff. The Science Inventory contains about 4,500 records, including 750 peer-reviewed products. Although many of these records pertain to ORD research products and activities, the Science Inventory also includes items provided by the Program

Offices and Regions. The initial records included in the Science Inventory were submitted following a call for data; now, there is a cross-Agency workgroup responsible for soliciting updates and input for the inventory. To demonstrate the search function of the Science Inventory, Mr. Zielinski entered the term "computational toxicology." Dr. Schnoor asked if EPA can distinguish hits to the site from downloads from the site. Mr. Zielinski replied that they cannot distinguish the difference; he added that it has had thousands of hits even though there has been some decline, likely because of the holiday season.

A search of the inventory yields a brief profile of the relevant records. This profile contains the objective/intended use, abstract, type of product, date the record was last revised, start and completion dates, Web address, contact information, cross-cutting issues, and the EIMS Record ID (if any). Additional information is included for peer-reviewed products. Complete copies of some products can be accessed through the EIMS database. Dr. Bostrom pointed out that the profiles do not provide citations for journal articles. Mr. Zielinski replied that the citation is included in the EIMS database for those products in both systems. Dr. Farland added that most articles can be downloaded from Science Direct.

Mr. Zielinski stated that EPA has used the system to respond to questions; for example, it was used to identify the research being done on the topic of atrazine. Dr. Henderson asked if the inventory uses the same search logic as PubMed. Mr. Zielinski replied that it is similar, adding that there is an online tutorial for the Science Inventory. Dr. Bostrom asked if there was a process for automatically collecting information; she referred to the fact that NERL's system feeds directly into EIMS. Dr. Bostrom also asked if the Science Inventory includes workshops. Mr. Zielinski responded that all data are not entered separately into the Science Inventory; data included on the NCER Web Site are automatically added to the system. He indicated that the inventory includes workshops as scientific activities rather than peer reviewed products, and stated that there are periodic checks to ensure that workshops and other activities have been included in the Science Inventory. Dr. Farland mentioned that the inventory identifies anticipated products, so it provides some information even before products are completed.

Dr. Dorward-King asked why EPA decided to make the Science Inventory available to the public. Dr. Farland responded that the inventory was initially a paper document that was designed as a tool to check the peer review process. EPA recognized that this would be a valuable tool for others so the inventory evolved to this public Web-based system over a period of 3-5 years. Dr. Schnoor asked if a search would yield all the products and activities of a particular Laboratory. Dr. Farland replied that the inventory was not designed for that purpose because the Agency prefers that each item be viewed as an EPA product or activity rather than one from a specific Laboratory or Center. Dr. Schnoor suggested that the citations for articles be included in the inventory profiles.

Mr. Zielinski said the Science Inventory received good reviews from OMB. He noted that there are plans to add more links to Agency databases and Web sites in the future. Dr. Farland suggested asking the BOSC Subcommittees if the Science Inventory was useful after they have completed their MYP reviews.

Endocrine Disruptors MYP Subcommittee Discussion

Dr. Harding reported that she received the Endocrine Disruptors MYP just a few weeks ago, so the Subcommittee members have had little time to review it. She noted that this program is being coordinated with the computational toxicology research program because EDC is the proof-of-concept study for that program. Dr. Harding introduced Dr. Elaine Francis (ORD/NCER), the NPD for Endocrine Disruptors, who is responsible for overseeing both the intramural and extramural EDC research programs.

Dr. Francis described the MYP for Endocrine Disruptors. Her presentation included a brief history of EPA's EDC research program, an overview of the MYP, some research highlights and coordination

efforts, and a list of upcoming activities. She began by defining endocrine disruptor and explaining why EPA is studying EDCs.

In 1994, EDCs were identified as an emerging public health and environmental issue at the Risk Assessment Forum Colloquium. In 1995, EPA organized and hosted two international research needs workshops and began developing a research plan for EDCs. In 1996, EDCs were identified as a high priority research area in ORD, and the first STAR program solicitation was issued. In 1997, an interim guidance document was published, and the second STAR program solicitation was issued. In 1998, ORD published a peer-reviewed research plan for EDCs, the third STAR program solicitation was issued, and EPA and NIEHS sponsored a grantees workshop. In 1999, EDCs were selected as a pilot for an MYP, and Dr. Francis was named the NPD for Endocrine Disruptors. In 2000, the fourth STAR program solicitation was issued, and in 2001, the first iteration of the MYP was finalized. In 2002, the second iteration of the MYP was completed, an EPA grantees workshop was held, a computational toxicology research program was developed in response to Congressional direction to develop alternatives to animal testing and EDCs was selected for proof of concept, and the first STAR program solicitation for computational toxicology research was issued. In 2003, the third iteration of the MYP was finalized, the second computational toxicology solicitation was issued through the STAR program, and a program review workshop on EDCs was held.

Dr. Francis pointed out that each of the ORD Laboratories and Centers plays a role in the EDC research program. EDC research has been supported by the STAR program since 1996. The extramural EDC portfolio includes 37 grants ($27.5 million) and the related computational toxicology portfolio includes 4 grants ($2.5 million). She noted that there are 18 additional grants ($4.6 million) relevant to EDCs funded under other programs. Solicitations will be issued on low dose and exposure issues as well as confined animal feedlot operations (CAFOs). Dr. Francis expressed interest in exploring partnership opportunities. Dr. Henderson noted that the grants appear to be rather small. Dr. Francis responded that most of them are funded at $100K-$150K/year for 3 years ($300K-$450K total). The grants for epidemiological studies are funded at $750K-$ 1 million/year for 3-5 years. She added that the EPA grants are funded at a level comparable to those funded by NIEHS and at a higher level than those funded by the National Science Foundation (NSF).

Dr. Francis identified the members of the EDCs MYP Planning Team, which included representatives from the five ORD Laboratories/Centers; Office of Science Policy (OSP); Office of Resource Management and Administration (ORMA); Office of Water (OW); Office of Prevention, Pesticides and Toxic Substances (OPPTS); Office of Air and Radiation (OAR); Region 2; Office of Solid Waste and Emergency Response (OSWER); and Office of Environmental Information (OEI). The MYP was written primarily by the ORD team members who worked closely with the Program Offices and Regions.

The MYP includes three long-term goals (LTGs): (1) provide a better understanding of the science underlying the effects, exposure, assessment, and management of EDCs; (2) determine the extent of the impact of EDCs on humans, wildlife, and the environment; and (3) support EPA's screening and testing program. Dr. Francis identified the questions for each of these LTGs, and presented three figures that depicted the linkages and timelines (FY 2003-FY 2012) for the Annual Performance Goals (APGs) to meet the three LTGs. She then illustrated how the APMs related to the APGs.

Dr. Francis explained that the schedules and sequencing in the MYP were based on existing resources, intramural capacity and capability, projected timelines for awarded grants, progress to date, complexity of the area, Congressionally driven deadlines, and relationship to other APGs and APMs in this and other MYPs. She indicated that the research in the MYP supports Agency Government Performance and Review Act (GPRA) Goal 4, Objective 4, Subobjective 4.1. She also identified the relationship between

the Agency's priorities and regulatory programs, noting that the MYP includes a combination of "problem-driven" and "core" research.

The MYP is closely linked to the research plan and the key MYP questions were taken from the research plan. The APG descriptions in the MYP include references to one or more of the 33 research plan subissues. Dr. Francis indicated that the MYP also includes the "MYP at a Glance," which identifies the emphases of the plan; the extramural program is focused primarily on effects. The MYP also includes guidance for implementation of the MYP, potential additional research should the budget be increased, and a description of the relationship of the MYP to non-EPA research programs.

Dr. Francis reviewed the draft charge to the BOSC regarding the MYP. The BOSC Subcommittee should comment on whether the MYP: (1) describes an appropriate implementation of the Endocrine Disruptors Research Plan; (2) clearly articulates ORD's unique niche; (3) provides sound rationale for its choices of emphasis; (4) focuses on the most appropriate LTGs and whether they demonstrate the path to the desired outcomes; (5) emphasizes the right issues and is sequenced appropriately; and (6) is flexible to adapt to future direction changes.

Dr. Francis presented a number of highlights of the EDCs research program. In support of LTG 1, providing a better understanding of the science, ORD has been determining classes of chemicals that act as EDCs and their potencies. The results of mode of action studies on atrazine (herbicide) and vinclozolin (fungicide) were critical to improving the Agency's risk assessments and setting tolerances. ORD is characterizing chemicals that alter testosterone synthesis or androgen receptor function, and investigating differential effects predictive of pattern of outcome. In addition, ORD is conducting studies on mixtures of phthalates with and without androgen receptor antagonists. Chemicals that affect the same tissue during sexual differentiation cause cumulative adverse effects regardless of the endocrine disruptive mechanism. The effects appear to be dose additive. ORD's research is determining the dose-response curves for EDCs at environmentally relevant concentrations, characterizing cellular and molecular mechanisms of abnormal reproductive development, and investigating exposure-effect relationships underlying alterations in pubertal development and adult reproductive function following developmental exposure to disinfection byproducts in drinking water. A new (third) estrogen receptor in vertebrates has been discovered and studies have demonstrated that estrogens and xenoestrogens can act on cells at the membrane level.

ORD is characterizing the effects of dioxin on matrix metalloproteinases through disruption of the steroid hormone signaling pathway, developing molecular indicators of exposure, and examining the ability to extrapolate across species. Also in support of LTG 1, ORD is identifying major sources of EDCs entering the environment, focusing on: contaminated sediments, wastewater treatment plants, CAFOs, sources of combustion, and drinking water treatment plants. ORD is developing tools for risk management of EDCs (e.g., biodegradation processes, pollution prevention strategies).

In support of LTG 2, determining the extent of the impact of EDCs, ORD has determined the levels of phytoestrogens in human amniotic fluid and the effects of exposure to those levels in animal models; is determining the magnitude of adverse impacts of EDCs on human health; developed methods to detect exposures to EDCs; and identified androgenic compounds in paper mill effluent, using a mosquitofish screening assay.

ORD is gathering evidence that EDCs are affecting wildlife at the individual level (e.g., effects of pulp mills on fish), and evidence that EDC effects in individuals are causing population-level effects (e.g., studying exposure and response of crocodile populations in Belize). Dr. Francis indicated that tools are needed to provide the linkage between population-level effects and diagnostic effects of EDC impacts. Also in support of LTG 2, ORD is applying molecular indicators of exposure, conducting human

exposure studies, and developing pilot-scale tools to assess risk management approaches. To put LTG3 into context, Dr. Francis gave an overview of Congressional mandates. The Food Quality Protection Act (FQPA) requires the screening of pesticides for estrogenic effects that may affect human health, and the Safe Drinking Water Act Amendments (SDWAA) of 1996 provide for the screening of drinking water contaminants to which substantial numbers of persons are exposed. On October 16, 1996, the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) was formed with 39 members representing broad consituencies. The members of EDSTAC were tasked with developing consensus-based recommendations for a screening program that would provide EPA with the information needed to make regulatory decisions about chemicals that disrupt the endocrine system. The EDSTAC recommended a two-tier screening framework. Tier 1 involves *in vivo* and *in vitro* screens to detect potential to interact with the endocrine system (androgen, estrogen, and thyroid). Tier 2 involves multi-generational reproduction and developmental studies covering a broad range of taxa. Only those products interacting with the endocrine system are subjected to Tier 2 screening. Tier 2 testing provides the data for hazard assessment.

Dr. Francis provided a timeline for the Endocrine Disruptor Screening Program (EDSP). The priority setting strategy was completed in 2002, and the initial list should be completed in 2005. Final regulations are expected in 2005, Tier 1 validation will continue through 2005, and Tier 2 validation beyond 2006.

In support of the LTG 3 of the MYP, supporting EPA's screening and testing program, ORD has developed improved QSAR and other computational approaches, male and female pubertal assays in rats, invertebrate (mysid shrimp) reproduction assay, receptor binding/transcriptional activation assays, aromatase assay, steroidogenesis assay, and fathead minnow assay. ORD also has evaluated the adequacy of the two generation mammalian reproductive study. In addition, ORD led the international validation process for the Hershberger assay, and is developing a frog metamorphosis assay (*Xenopus* metamorphosis model for thyroid system disruption).

Dr. Francis pointed out that the broad and complex nature of the EDCs issue necessitates a coordinated effort on both the national and international levels. ORD's program is coordinated across the federal government through involvement in the CENR Endocrine Disruptors Working Group, which was first convened in 1995. EPA chaired this working group that includes representatives from 14 federal agencies. The working group developed a research needs document and an inventory of federal research, established national priorities, and co-sponsored two multi-agency requests for RFAs for extramural grants.

EPA's EDCs research program is coordinated internationally through a number of mechanisms. EPA has ensured that EDCs has been on the agenda of the annual G-8 Environmental Ministers Meeting since 1997. EPA also chaired the International Programme on Chemical Safety/World Health Organization (WHO)/Organization for Economic Co-operation and Development (OECD) Steering Committee, and led the development of a Global Endocrine Disruptors Research Inventory and a "Global State of the Science" report (WHO, 2002). In addition, EPA is working with the European Union and Japan to promote scientific collaborations; participating on OECD work groups to develop, validate, and harmonize screening and testing guidelines; and sponsoring workshops among environmental groups, federal agencies, and the chemical industry.

In the next year, ORD will determine the progress made in addressing the 10 key research questions identified at the October 2003 Program Review Workshop, learn how research results are being applied by the Program and Regional Offices, determine where critical data gaps remain and whether changes in direction or emphasis are needed, identify potential collaborators, and determine the best approaches to communicating research results. ORD plans to identify topics and prepare a series of synthesis documents that integrate intramural and extramural research. These documents will address key research

questions, provide valuable input for development of the next MYP, help document ORD's progress, and inform EPA staff, the scientific community, and other federal agencies about the Agency's efforts. ORD also will be launching a new Web site that will provide links to all Laboratories/Centers and Program and Regional Offices that have EDC Web pages, as well as other relevant sites. The research plan, MYP, bibliography, synthesis documents, press releases, fact sheets, and other products will be posted on this site. ORD will coordinate its efforts with the new CENR working group. Proposed joint efforts include: evaluating progress made in addressing high priority critical research gaps, convening a workshop to discuss progress on the 12 epidemiology studies, convening an expert panel to provide advice on directions for exposure-related research, issuing a joint solicitation, developing the next generation database of federal research inventory, and facilitating collaborations with other countries/international organizations (e.g., Japan, European Union). Also in the next 12 months, ORD will prepare for the Program Assessment Rating Tool (PART) review by OMB (June 2004), and update the MYP following the BOSC review.

Dr. Francis presented a diagram of the endocrine disruptors research program design logic model that identified the outputs and outcomes of the program. In summary, she stated that there is global concern regarding exposures to some environmental agents that interfere with endocrine systems. EPA is a leader in national and international efforts to coordinate EDCs research, and the Agency's research is providing immediate results for implementing the screening and testing program mandated by the FQPA and SDWAA. EPA's long-term research program on EDCs focuses on the most critical uncertainties in: determining whether humans and wildlife populations are being impacted by levels of EDCs in the environment, identifying the sources of those exposures, and developing approaches to reduce/prevent them.

Dr. Harding stated that she is comfortable with the charge to the BOSC. She indicated that the Subcommittee will need the expertise of a developmental endocrinologist or someone who has been working in the area of EDCs for some time. The Subcommittee also needs a wildlife biologist and an epidemiologist with expertise in biomarkers and human exposure. Drs. Gaston, Lambert, and Francis agreed to provide some names to Dr. Harding for consideration. Dr. Harding asked if individuals who receive EPA funding should be excluded from the Subcommittees. Dr. Schnoor replied that it should not preclude them; however, if there are candidates with similar qualifications who are not receiving EPA funding, then they should receive preference. Before recessing the meeting for the day, Dr. Schnoor asked the BOSC members to review the minutes before the meeting reconvenes in the morning.

Friday, January 23, 2004

Approval of the September 2003 BOSC Meeting Minutes

Dr. Schnoor called the meeting to order at 8:30 a.m., and asked for comments on the September meeting minutes. Dr. Bostrom asked that the second to the last sentence in the first full paragraph ("In addition, risk communication is not a management issue") on page 4 be deleted and that ", however," be deleted from the next sentence. She also asked that "cold" be changed to "could" in the sixth line of the second full paragraph on page 5. Dr. Henderson asked that the word "social" be replaced by the word "behavioral" on page 8. Dr. Schnoor pointed out that the Subcommittee members identified on page 9 are no longer correct. Because Dr. Chameides is no longer a member of the BOSC, he will not be serving on the Global Change MYP Subcommittee. Dr. Schnoor will be replacing Dr. Chameides on that Subcommittee rather than serve on the Computational Toxicology Subcommittee. Dr. Schnoor also asked that the word "total" be inserted before $80 million in the fourth line in the second to the last paragraph on page 11. Dr. Johnson asked that the fourth action item listed on page 23 be retained as an action item for this meeting. When there were no other comments on the minutes, Dr. Schnoor asked for a motion to

approve them with the requested revisions. Dr. Bostrom moved that the minutes be approved, and Dr. Stewart seconded the motion. The September minutes were approved unanimously by the BOSC.

BOSC Issues

Dr. Farland commended Shirley Hamilton, who retired in January, for her service as the DFO for the BOSC. He also welcomed Ms. Kowalski as the new DFO, and thanked Dr. Lambert for his willingness to serve as the liaison to the BOSC from the SAB. He asked Dr. Lambert to provide an update on SAB activities at the May BOSC meeting, and Dr. Lambert agreed. Dr. Gilman will be sending a recommendation to the Administrator's office that Dr. Johnson replace Dr. Schnoor as the BOSC Chair. Dr. Farland hoped to make the transition to the new Chair at the May meeting, and he assured Dr. Schnoor that ORD will respond to all of the products submitted by the BOSC under Dr. Schnoor's tenure as Chair before the May meeting. Dr. Farland said that the BOSC charter must be renewed in May 2004. He believes that the current language of the charter provides sufficient flexibility and did not propose any changes.

Dr. Farland said that would like the BOSC to provide timely advice to the Laboratories and Centers and on ORD programs. He suggested that the Computational Toxicology Subcommittee may be a good model for the future. Dr. Farland mentioned that ORD is in the process of recruiting the new BOSC members. He noted the need to identify some social/behavioral scientists and air pollution experts for consideration. In addition, Dr. Gilman believes that adding an expert in evaluation techniques would be beneficial (to assist with figuring out how to measure success).

Dr. Farland asked if the BOSC preferred to receive materials prior to the meeting, and most members indicated that they would prefer to receive the materials about 2 weeks in advance. Many of the members expressed their preference for the smaller notebooks. The materials could be distributed via e-mail or posted on the BOSC Web Site for download. If the materials are posted to the Web site, an e-mail will be sent to all BOSC members informing them that the materials for the upcoming meeting have been posted. Dr. Harding asked that e-mailed documents be sent as Word files rather than as WordPerfect files. Ms. Kowalski assured the BOSC members that this request could be accommodated easily.

The next BOSC meeting will be held in Research Triangle Park, NC, at EPA's new facility. The meeting agenda will cover 2 full days, May 13-14, 2004, and will include a tour of the new facility, probably on Thursday afternoon. The tour should include a demonstration of the Laboratory's high-performance computing capability. As previously mentioned, ORD has been working to reduce the time required to run some of the data intense air models.

Dr. Farland asked if the BOSC wanted to consider organizing a risk assessment workshop, as was suggested by Dr. Henderson at the September meeting. Dr. Henderson said that her suggestion arose because risk communication was not addressed at the May Communications Subcommittee workshop. Dr. Schnoor noted that the BOSC has significant expertise in risk assessment and the members have expressed interest in this topic.

The nine NPD positions are being advertised on the Web, in professional journals, and at upcoming meetings. The deadline for applications is April 16, 2004. These are Scientific/Technical Professional positions with pay rates that exceed the GS-15 pay scale. Dr. Farland commented that the new NPD positions will have expanded roles and responsibilities. These positions will be comparable to the Laboratory/Center Director positions. Dr. Farland asked the BOSC members to encourage qualified candidates to apply. Dr. Daston asked if the BOSC could receive information about the number of applicants. Dr. Farland responded that such information could be provided and he agreed to update the BOSC on this issue at the next meeting. Dr. Johnson said that as a member of the SAB, he automatically

received the announcement advertising the National Program Director positions. Can the BOSC members be added to the list to receive such announcements? Dr. Farland replied that he will discuss it with Ms. Kowalski and report back to the BOSC. Dr. Farland encouraged the BOSC members to visit the ORD Web site between meetings; the site has current news, new documents, announcements, events, and many other useful items.

Public Comment

Gary Kayajanian asked the BOSC members to consider publishing some of their papers as SGEs. This would make more papers available online because government employees do not have to relinquish the copyright to the publisher.

Global Change MYP Subcommittee Discussion

Dr. Dorward-King introduced Dr. Mike Slimak (ORD/NCEA) and Dr. Joel Scheraga (ORD/NCEA) who agreed to present an overview of the Global Change MYP. Dr. Slimak provided a brief history of the ORD Global Change Research Program, stating that ORD has been involved in global change research since 1990, when the Clean Air Act Amendments (CAAA) were passed. About one-third of the program's $22 million budget is allocated to extramural grants (STAR program), another third to salaries of EPA staff and intramural research, and the final third to contractor support and cooperative efforts. The program originally focused on process-based research. An integrated strategy was published in 1996, and it was peer reviewed in 1997. The reviewers noted that the program lacked focus, was duplicative of the efforts of other agencies, and lacked an overall management scheme. In response to this review, ORD decided to reorganize the program to one that was more assessment-based. A new *Research Strategy* for ORD's Global Change Research Program was produced in 2000, and subsequently favorably reviewed. In 2000, the Office of Science and Technology Policy (OSTP) took a leadership role in the First U.S. National Assessment of global climate change. ORD rewrote the strategy in 2000, and it was peer reviewed in 2001. The reviewer comments were favorable and they strongly endorsed the shift from process-based to assessment-based research. The strategy was revised in response to the review comments and the revised strategy is available on the ORD Web Site. In February 2002, President Bush announced the formation of the U.S. Climate Change Science Program (CCSP) to coordinate efforts across the federal government. (The CCSP consists of the Congressionally mandated U.S. Global Change Research Program and the President's Climate Change Research Initiative.)

Representatives from the federal agencies worked together to develop a *Strategic Plan* for the CCSP. This is the first government-wide plan ever published and released on this issue. Dr. Slimak reported that ORD was heavily involved in the development of this strategy, and the MYP is consistent with this government-wide strategic plan. The Global Change MYP was completed approximately 12 months ago and is in need of an update. He hopes to use the input from the BOSC, along with comments from ORD staff, to revise the MYP.

Dr. Scheraga, National Program Director for the Global Change Research Program explained that the key external driver for ORD's research program is the CCSP, which includes 12 federal agencies. EPA fills a specific niche within the CCSP by focusing on the assessment of the potential consequences of global change for air and water quality, ecosystems, and human health; the evaluation of adaptation options; and the provision of timely and useful information to decision makers and the development of decision-support tools. He noted that the CCSP enables close coordination with other federal agencies (e.g., NOAA) and elimination of duplicative activities.

The new CCSP *Strategic Plan*, a long-term plan to enhance scientific understanding of climate change, was released in July 2003. This plan accelerates research to provide scientific information to support

decision making, and it has undergone extensive public and NRC reviews. The ORD Global Change MYP is closely tied to the CCSP *Strategic Plan*, and the CCSP *Strategic Plan* and accompanying peer review comments strongly support the work contained in ORD's Global Change MYP.

The *Research Strategy* for ORD's Global Change Research Program was peer reviewed in February 2001, and the revised strategy was finalized in December 2001. The strategic vision for the program includes the conduct of both issue-based (e.g., air and water quality) and place-based (e.g., Great Lakes, Gulf Coast) assessments. Place-based studies provide a logical means for integration of air, water, ecosystem, and human health effects, and are naturally suited to information requirements of decision makers, which often are unique to a specific location. ORD's research strategy defines roles for each Laboratory and Center.

Dr. Scheraga provided a brief overview of the planned research and assessment activities in each of the four "focus areas" of the program (i.e., air, water, ecosystems, human health). The air quality assessment activities include an investigation of regional weather patterns and climate change; global change effects on emissions (anthropogenic and biogenic); and societal change, technological advances, and emissions. In the area of water quality, ORD already has completed initial assessments of the effects of climate change and land use change on pollutant loads, as well as the impacts of storm surge and sea level rise on water supplies. ORD also is investigating the implications of global change for biocriteria. In the area of global change and ecosystems, ORD has completed a problem formulation report on aquatic ecosystems (watersheds, estuaries, and corals). ORD is studying the protection of ecosystem services and plans to examine the effects of global change on invasive nonindigenous species. In the area of global change and human health, ORD has completed a study of weather-related morbidity (heat stress and accidental injury). Initial assessments of water and vector-borne diseases have been completed, and there are plans to study the implications of global change for airborne allergies and air pollution health effects.

Dr. Scheraga commented that although ORD's primary focus is the United States, the program has to consider transboundary issues. He noted that EPA is very involved with international organizations. For example, EPA was a major contributor to the WHO book, *Climate Change and Human Health—Risks and Responses*, published in 2003. Several Board members asked for a copy of that publication, and Dr. Scheraga agreed to provide copies to the BOSC. Dr. Harding asked if EPA is working with NIEHS' centers on oceans and health. Dr. Scheraga replied that there has not been interaction to date, but he expected there will be in the future. He noted that these centers are not mentioned in the MYP because they were recently created. He assured the BOSC that EPA will make that connection. Dr. Farland added that EPA is in the process of signing an MOU with NSF and NOAA to work on oceans and health. Dr. Johnson pointed out that ORD's place-based assessments did not include oceans. This appears to be a significant gap in the plan. Dr. Scheraga replied that each agency has taken ownership of different issues, sectors, and regions and the oceans are covered by other agencies. ORD's focus is aquatic ecosystems, but EPA is coordinating with other agencies that are working on terrestrial and marine ecosystems. The challenge is ensuring that the other agencies conduct their research in a timely fashion to ensure that the results are available when they are needed by EPA. Dr. Farland commented that there has long been a split between oceans and estuaries and rivers; however, the new belief is that they need to be studied in an integrated manner.

STAR grants provide ongoing, long-term support for selected topic areas, and augment areas in which ORD has expertise. The grants are focused on a limited number of topic areas consistent with the long-term Global Change Program's *Research Strategy*. More specifically, the grants are intended to provide the science to support the planned air quality and ecosystem assessments. Dr. Scheraga said that EPA cannot do the required research alone; the required assessments go far beyond the expertise and resources of the Agency. For example, the Agency is cooperating with universities, research institutions, and other agencies that have additional expertise in air quality modeling, as well as the assessment of terrestrial and

marine ecosystems. EPA is grappling with the issue of downscaling Global Circulation Models so they can be applied to assessments in regions and communities, and is working with the National Center for Atmospheric Research (NCAR), Battelle, and Johns Hopkins on this issue. Dr. Dorward-King asked how ORD ensured that the required results would be available when they are needed by the Agency. Dr. Scheraga replied that EPA issues carefully written RFAs that are targeted at very specific scientific questions and makes awards in the form of cooperative agreements that permit EPA to work closely with the outside investigators. EPA also holds workshops to allow the researchers to interact and share information in a timely fashion.

Dr. Scheraga stated that the statements and findings of external scientific bodies—the Intergovernmental Panel on Climate Change (IPCC) and the NRC have confirmed that ORD's Global Program is focusing on the right scientific questions and directions. The stakeholder orientation of ORD's program also helps ensure that it provides timely and useful information to decision makers, resource managers, and other stakeholders. It also requires that ORD elicit the questions of concern to stakeholders and the time frame in which they need the information, and fosters development of a research agenda that is focused on producing timely and useful information. ORD also conducts its assessments through public-private partnerships that include stakeholders and decision makers throughout the process.

To illustrate how stakeholders are engaged in the program, Dr. Scheraga used the Great Lakes assessment activities as an example. The Great Lakes Regional Assessment team hosted workshops to evaluate how assessment findings can inform decision processes and to elicit new information needs. These workshops, conducted from March 2001 to October 2002, focused on Great Lakes water levels, lake ecology, agriculture, terrestrial ecology, and recreation. The results derived from these discussions is being used to orient and focus the next phase of assessment activities in the Great Lakes Region.

Dr. Scheraga noted that the MYP is an implementation plan for the long-term vision articulated in the program's *Research Strategy*. It provides critical paths to accomplish the work outlined in the strategy. The MYP identifies five LTGs, and accompanying APGs and APMs, for the Global Program. The MYP identifies annual responsibilities of the Laboratories and Centers, including specific research and assessment activities, APMs, and products. Dr. Scheraga noted that this is an integrated program with some, but not all, deliverables dependent on products from various Laboratories/Centers. To illustrate this, he presented a table that contained a time line of annual responsibilities of ORD Laboratories and Centers (captured in APMs) required to complete an air quality assessment (captured as an out-year APG).

Dr. Scheraga discussed the usefulness of the MYP in practice to date. He reported that the MYP has been an effective tool for research planning. It is driving ORD towards more integration, linking research and assessment activities to the GPRA process, and helping ORD identify priority research, which aids the budgeting process. He noted that the MYP is a living document that is to be updated on an ongoing basis to reflect ORD's experiences, changes in the state-of-the-science, new administration priorities, and changing client needs. Dr. Scheraga pointed out that the MYP is already out of date and is being revised. Feedback from the BOSC review will help to guide these revisions. In addition, ORD will continue to ensure that the revised MYP is consistent with the CCSP *Strategic Plan*, and reflects ongoing progress and insights. Dr. Scheraga mentioned that the CCSP *Strategic Plan* commits the federal government to producing 21 Synthesis and Assessment Products in the next 2 to 4 years. EPA is the Lead or Co-Lead Agency for three of the products, and is supporting the production of seven others.

Dr. Dorward-King asked about the extent of EPA's economic analysis efforts. Dr. Scheraga replied that much of the economic impact work of the assessments is done outside ORD, by the National Center for Environmental Economics (NCEE) in the EPA Office of the Administrator. Additional economic impact work is conducted through STAR grants. Dr. Dorward-King asked if economic impact analysis is part of

EPA's charge, and Dr. Scheraga replied that it is, and there are no other agencies doing such work within the CCSP. Dr. Schnoor asked about mitigation, and Dr. Scheraga responded that EPA is not permitted by CCSP to address mitigation issues. Therefore, ORD has not included mitigation in its research program; however, EPA's Office of Air Programs does some work in this area. He added that the NRC recommended that the CCSP look at mitigation issues, so the idea is under consideration.

Dr. Lambert asked if the BOSC should identify ways to strengthen interagency relationships and cooperation. He noted that improved coordination is a good way to do more for less. Dr. Schnoor asked Dr. Vanessa Vu (EPA/SAB Staff Office) if the SAB has looked at improving interagency cooperation. She replied that she did not think the SAB has examined this issue. Dr. Scheraga commented that the NRC is looking at this issue in the ongoing review of the CCSP *Strategic Plan*. Dr. Clegg said the MYP should include a communication plan. Dr. Daston expressed interest in how EPA is sharing data with the other agencies involved in global change research. He noted that the BOSC could provide advice on how to make that process more transparent.

Dr. Dorward-King indicated that the Global Change Subcommittee needs additional expertise in atmospheric fate and transport, human health/public health (tropical diseases and vector-borne diseases), modeling (with a climate focus), and economics/social science. She thought that at least three experts should be added to the Subcommittee. She hopes to have the Subcommittee formed and the first meeting completed before the May BOSC meeting. Dr. Farland pointed out that such a short time frame would necessitate the use of SGEs on the Subcommittee. Dr. Dorward-King asked the BOSC members and EPA staff to provide names of appropriate individuals to her as soon as possible. She would like to include some experts from other federal agencies if possible. Dr. Farland mentioned that there is a PART review scheduled this summer for the ORD Global Program, so timely BOSC feedback would be very helpful.

EPA Science Advisory Board Reorganization

Dr. Vanessa Vu thanked Dr. Schnoor for the introduction. She indicated that the last time she addressed the BOSC was when she was with ORD's National Center of Environmental Assessment (NCEA). Since June 2002, she has served as Director of SAB Staff Office, as Dr. Donald Barnes had retired. Dr. Vu described the overall functions of the Staff Office, and the missions and membership of the three EPA advisory committees that her office manages and supports—the SAB, CASAC, and the Council. She then provided an overview of the new structural organization of the SAB, and the SAB advisory projects for FY 2004. Dr. Vu indicated that she is looking forward to more coordination with the BOSC as the SAB undertakes these FY 2004 advisory projects.

The SAB Staff Office manages and provides technical and administrative support to three EPA Federal Advisory Committees: Clean Air Scientific Advisory Committee (CASAC), Advisory Council on Clean Air Compliance Analysis (Council), and Science Advisory Board (SAB). The Staff Office sets the advisory agenda in consultation with EPA Offices and the advisory committees, ensures that advisory activities follow Federal Advisory Committee Act (FACA) and other federal requirements, and interfaces between the advisory committees, other EPA Offices, and the public. The goals of the SAB are to provide timely, balanced, relevant and useful advice and products, and have a positive impact on how EPA does science and uses science in protecting public health and the environment.

The CASAC was established in 1977, under the CAAA to provide advice to the Administrator regarding air quality standards of criteria pollutants, research related to air quality, sources of air pollution, and strategies to attain air quality standards and to prevent significant deterioration of air quality. The chartered Committee is composed of seven members. The Council was established as mandated by the 1990 CAAA to provide advice to the Administrator regarding EPA's analyses of the impacts of the CAA on public health, economy, and the environment. The chartered Council is composed of at least 9

members; presently, there are 15 members. The SAB was established in 1978 by the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA) to provide independent advice to the Administrator on scientific and technical matters underlying key environmental policies and risk management decisions. The chartered SAB is composed of at least 9 members; presently, there are 33 members.

The SAB was reorganized recently. The new SAB structure includes the Board, the Quality Review Committees, Standing and *Ad Hoc* Committees, and *De Novo* Review Panels. There currently are seven Standing Committees: Drinking Water Committee, Environmental Economics Advisory Committee, Environmental Engineering Committee, Ecological Effects and Processes Committee, Environmental Health Committee, Integrated Human Exposure Committee, and Radiation Advisory Committee. In addition, there are four *Ad Hoc* Committees: Scientific and Technological Achievement Awards Committee, Committee on Valuing the Protection of Ecological Systems and Services, Bioethics Advisory Committee, and Homeland Security Advisory Committee.

The SAB coordinates with a number of advisory committees including: CASAC, Advisory Council on Clean Air Compliance Analysis, Scientific Advisory Panel, Children's Health Protection Advisory Committee, and Board of Scientific Counselors.

The members of the CASAC, Council, and SAB and its Committees are appointed by the EPA Administrator. The members are distinguished scientists, engineers, economists, and social scientists drawn from academia; federal, state and tribal governments; industry; and NGOs. The Staff Director appoints consultants to provide additional expertise as needed. As SGEs, members and consultants are subject to all relevant federal requirements, including conflict of interest regulations.

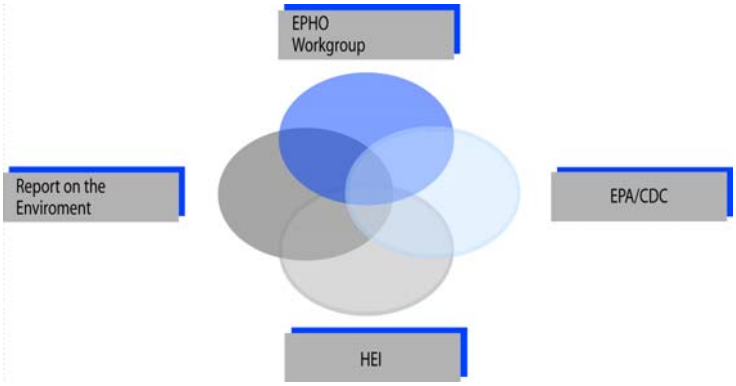
In FY 2004, the SAB will undertake 33 advisory projects, including 16 for ORD, 6 for OAR, 2 for OW, 1 for OSWER, 2 for OPPTS, 1 for OEI, 1 for Office of the Chief Financial Officer, 1 for Region 5, and 3 for Office of Policy, Economics, and Innovation (OPEI). The products to be reviewed include 16 assessments, 5 guidance and guidelines, 3 tools and methods, 6 research/science strategies or plans, and 3 other items. Some examples of the products reviewed by the SAB are: National Ambient Air Quality Standards for Criteria Pollutants, Report on the Environment, Economic Research Strategy, and Guidance on Carcinogenic Risks to Children.

Dr. Vu presented a diagram that depicted the SAB advisory project cycle. She then identified a number of steps to enhance the quality and timeliness of the advice and report. These steps are: (1) increased use of existing Committees supplemented with needed expertise from other SAB or EPA FACA Committees, (2) charge questions that are focused and clear; (3) prompt distribution of EPA advisory materials; (4) prompt provision of additional resources to shorten the time for report preparation; (5) letters to the Administrator that contain lay language and focus on the bottom line and more concise reports; (6) advanced scheduling of quality review and approval by the Board; and (7) increased use of public teleconferences.

Dr. Schnoor thanked Dr. Vu for her presentation and mentioned that there had been some discussion about the BOSC and the SAB collaborating on the MYP reviews. The SAB is reviewing the Particulate Matter (PM), Ozone, Contaminated Sites, Safe Food, and Drinking Water MYPs. Although these reviews have not been scheduled, the Drinking Water MYP review will be initiated soon. The SAB may coordinate the reviews of the PM and Ozone MYPs with CASAC and perhaps the BOSC. Dr. Schnoor thought it might be helpful to inform the SAB of the types of expertise required for the BOSC Subcommittees.

Accountability Initiative—Assessing the Public Health Impact of Environmental Decisions

Dr. Hal Zenick (ORD/NHEERL) indicated that the accountability concept was first integrated into ORD planning with its incorporation into the Human Health Research Strategy (HHRS) in 1998; and thus predates the current Agency initaitive. The HHRS covers four areas: (1) harmonizing risk assessment approaches, (2) aggregate and cumulative risk, (3) susceptible populations, and (4) accountability. The accountability component of the HHRS involves the use of health and exposure indicators to assess the effectiveness of environmental-decision-making. The SAB review of the HHRS indicated that, although the inclusion of accountability was a step in the right direction, the strategy focused on very broad measurements. The SAB recommended that EPA devote considerable thought and effort to accountability before moving ahead with formulation of a research plan. Dr. Zenick identified four, concurrent, interdependent activities that are providing the underpinnings for the accountability initiative:



In the **EPA Report on the Environment** (ROE), then EPA Administrator Whitman wrote: "It is also important that we hold ourselves accountable to the American public and report to them our progress in reaching the goals we have set for ourselves ….to describe the condition of critical environmental areas and human health concerns." "To verify the protective benefit of environmental decisions and to maintain public confidence in those decisions and their associated costs, the Agency must be able to show that its actions result in demonstrable improvements in ecological and human health and that those actions are cost-effective." The ROE describes what the Agency knows and what it does not know. It identifies measures/indicators to report on the status of national environmental conditions and trends and, where possible, their impacts on human health and the environment. The report also discusses the challenges that the nation faces in improving these measures. The first ROE was released in spring 2003, and it was a milestone in the Agency's experience in developing and using indicators. Efforts have begun to lay out the potential vision, goals, and objectives to improve EPA's reporting and use of indicators. The Agency is considering a variety of 2004 actions for improving the next ROE in terms of both process and content.

In 2003, the **Health Effects Institute** (HEI) published a monograph that provides a framework for understanding and assessing accountability. The monograph, which was prepared by multiple authors led by John Samet at Johns Hopkins, also included research recommendations. The HEI has issued an RFA that seeks studies designed to assess health impact of regulatory or non-regulatory actions that improve air quality.

On September 30, 2003, EPA signed an MOU with the Department of Health and Human Services (DHHS) represented by the **Centers for Disease Control and Prevention (CDC)** to: (1) advance efforts

to achieve mutual environmental public health goals; (2) strengthen the bridge between the environmental and public health communities; and (3) achieve better understanding between environmental hazards, ensuing exposures, and health effects. The cornerstone of the MOU is cross-institutional initiatives to link environmental and health information sources, namely EPA's National Environmental Information Exchange Network and CDC's National Environmental Public Health Tracking Network. For the National Environmental Information Exchange Network, the states and EPA are committed to a partnership to build locally and nationally accessible, cohesive and coherent environmental information systems. The network will ensure that both the public and regulators have access to the information to document environmental performance, understand environmental conditions, and make sound decisions that ensure environmental protection. The mission statement of CDC's National Environmental Public Health Tracking Network is to be better prepared to develop and evaluate effective public health actions to prevent or control chronic and acute diseases that can be linked to hazards in the environment. With appropriations of $17.5 million in FY 2002, CDC funded 17 states, 3 local health departments, and 3 schools of public health to begin development of a national environmental public health tracking network and to develop capacity in environmental public health at the state and local levels. In FY 2003, CDC issued its second RFA.

CDC's National Human Exposure Report, issued in spring 2003, presents exposure levels on 127 chemicals. It is anticipated that this report will be issued on a biannual basis. Additional nominations for the next issue have been solicited, and a recent *Federal Register* notice reflects inclusion of a substantial number of EPA's nominations. Dr. Zenick pointed out that biomonitoring data (i.e., dose) are critical for the business of EPA because they support quantitative risk assessment and effective risk management and pollution prevention efforts, if it is possible to reconstruct links back to sources. Over time, the report will provide a stable picture, including exposure in certain subpopulations. The challenge, however, will be in translating the data.

CDC's National Human Exposure Report will be useful in assessing the impact of regulatory decisions and actions. The report will rely on "outcome" indicators to compliment traditional process indicators. Dr. Zenick noted that this report may be the earliest reflection of success of national-level policies, and the report may help refine/redirect policies and priorities. However, the ability for "outcome" indicators to serve as surrogates for actual improvements in health outcomes remains to be proven.

ORD's **Environmental Public Health Outcomes Workgroup** held an interagency workshop to obtain feedback from other organizations, become familiar with their complimentary efforts, and explore possible collaborative opportunities. Dr. Zenick provided some examples of potential research directions:

1. Mining of existing databases—challenges in integrating retrospectively environmental and health databases.

2. Translational research to better understand the significance of data currently collected from monitoring or surveillance systems. Of special interest is the interpretation of biomonitoring data.

3. Prospective studies that develop and demonstrate the predictive validity of exposure/outcome indicators in human populations.

4. The reality of multistressors—dissecting the risk that can be attributed to the exposure of interest.

5. The application of emerging technologies (e.g., "omics") and modeling to understanding these linkages.

Dr. Zenick presented a diagram that illustrated the accountability challenge, and stated that the most profound impact may be the efforts to begin to rebuild the partnership between environment and public health. He provided some examples of the growing partnership, including participation of both environment and public health organizations at the Institute of Medicine Workshop in April 2002; EPA participation on CDC workgroups on the National Environmental Health Tracking Initiative; CDC and EPA MOU and Workgroup; EPA interactions with the Council of State and Territorial Epidemiologists, National Association of County and City Health Officials, and Association of State and Territorial Health Officials; DHHS review of EPA's Report on the Environment; extensive engagement of EPA on candidate chemicals for the National Human Exposure Report/National Health and Nutrition Examination Survey (NHANES); and a potential co-funded RFA in FY 2004.

Dr. Daston commented that publishing the data in CDC's National Human Exposure Report without interpreting the results is a public relations nightmare for the chemical industry. Dr. Zenick said that currently there is no interpretation offered in the report that is useful for environmental and public health officials. Dr. Henderson asked if the chemicals on CDC's list include only parent compounds, and Dr. Zenick replied that putative metabolites are included as well.

Dr. Harding said she is working with Oregon's Public Health Steering Committee and work is just getting started. The committee plans to examine California's tracking efforts before developing Oregon's system. Dr. Henderson asked if there were any plans to improve the tracking of health data. She added that CDC has awarded several grants to determine if it is possible to track health outcomes. Dr. Farland said that EPA has a good idea of the types of health data needed. He mentioned that Iceland has an incredible database on health outcomes that has been linked to genetics and genomics databases. They plan to link the outcomes database to environmental exposure data to determine if it is possible to identify exposure effects.

Dr. Daston urged EPA to link hazard and exposure information; this link is very important for effective decision making. Just because biomonitoring data on a chemical are available, it does not mean that the chemical poses a significant risk. Dr. Lambert added that there are limited data on the health effects of many chemicals. He asked if EPA was involved in reviewing the applications funded by the CDC, because a number of the states that received grants have very little environmental monitoring. Dr. Zenick responded that EPA was only peripherally involved in the review and awards. Dr. Kevin Teichman (ORD/OSP) said that EPA is very interested in pursuing such involvement.

Dr. Preuss asked Dr. Daston to clarify his comment about the CDC report. Dr. Daston explained by using phthalates as an example. The reproductive effects of phthalates are of concern and these data could be linked to the information collected by CDC. It also would be helpful to include some pharmacokinetic determinations. All of these data should be communicated simultaneously with the exposure information. Dr. Zenick agreed that it would be better to put published data in context. Dr. Schnoor pointed out that it is not always possible to reach agreement about exposure. He thinks that it is better for EPA to publish the data and do the best job possible to interpret the information. Dr. Lambert commented that it is important to inform the public of what is known and unknown, as well as identify the critical information needs. Dr. Farland said that there are some examples in the literature for local situations where a change in exposure is linked to health outcomes. Could these be extended to make recommendations for improving outcomes? How do we move up the scale from these anecdotal or case-type evaluations?

Future BOSC Business Discussion

Dr. Johnson distributed copies of the revised charge questions that were prepared by himself and Drs. Bostrom and Henderson. He believes that the revised list of seven questions covers all of the pertinent issues and brings consistency to the three MYP charges. He noted that this should make it easier to identify any common themes. The revised charge questions are:

1. The proposed scope of work is consistent with:
   a. ORD's subject area research strategy
   b. The current state-of-the-science
   c. Research by others

2. The science questions address the most important scientific gaps and uncertainties in the subject area.

3. The long-term goals are relevant to the science needs of the Agency, and the MYP situates the annual research products (APGs, APMs) on a clear path to accomplishing each of the LTGs (and the APMs contribute to the APGs).

4. Research products and emphases over the next 5-7 years are sequenced appropriately to accomplish goals and meet program and regional needs.

5. The MYP is flexible enough to adapt to future science and policy changes.

6. The MYP articulates a strategy that facilitates effective communication and utilization of research products (with both domestic and international parties).

7. There is a clear path for assessing/evaluating the MYP and progress toward its goals.

Dr. Bostrom said she was told that only some APMs are included in the GPRA documents. Which planning documents are used for assessment, and how are they used? Dr. Farland replied that there are GPRA reporting processes at the Congressional level, Agency level, and ORD level. The top tier activities are evaluated, but there are other efforts that are measured as well. These are used by OMB and Congress.

Dr. Lambert asked if it would be appropriate for the BOSC to comment on the funding level for the programs. Dr. Johnson noted that only the cumulative figure is provided in the MYPs. Dr. Farland reminded the BOSC members that the funding is assumed to be flat in future years in the MYPs, and because MYPs are not budget documents, there is no detail on funding levels. Dr. Teichman stated that the MYPs identify areas for which funding is expected to increase and areas for which funding is expected to decrease, as well as the expected timing of these shifts. The BOSC could recommend a shift in the funding emphasis if that seems appropriate.

Dr. Farland asked about the next steps. Dr. Johnson replied that the seven revised questions should replace the questions in the current draft charges. He indicated that there are no changes to the front-end material of the charges. Dr. Bostrom noted that each Subcommittee will have additional self-study questions to be addressed by ORD. Dr. Schnoor asked the Subcommittees to develop and submit those questions quickly, as well as requests for materials to review and a list of individuals to be interviewed.

Dr. Daston said that he will prepare a charge for the Computational Toxicology Subcommittee that will lay out the parameters for advising ORD on the research strategy (e.g., does it align with Agency needs,

emphasize the right areas, plan for communicating results, impact on risk assessment?). The questions will be prospective, and the site visit probably will be held at NHEERL.

Dr. Schnoor asked the Subcommittee Chairs to submit their lists of names for potential Subcommittee members to Ms. Kowalski as soon as possible. He also asked them to give some thought to the locations for the site visits and the possible dates. In addition, the Chairs should provide Ms. Kowalski with an estimate of person days required for the review.

Dr. Farland provided an update on the Homeland Security Strategic Plan. He asked if the BOSC wanted to pursue this issue, given the ongoing MYP reviews. Dr. Schnoor responded that the BOSC is very interested in this topic and would like to be involved. Dr. Johnson asked what products would be ready for review by fall 2004. By then, the BOSC should be able to devote some time to homeland security. Dr. Farland will pose that question to Tim Oppelt (ORD/National Homeland Security Research Center), and provide his answer at the May meeting.

Dr. Bostrom asked about the status of ORD comments on the Communication Subcommittee report. Dr. Farland replied that Michael Brown had a few comments, and Dr. Bostrom has already addressed them. Ms. Kowalski agreed to contact each of the Laboratory/Center Directors to request their comments by January 30. She will provide the comments received to Dr. Bostrom so that the report can be revised as necessary. Dr. Bostrom said that, although she will be rotating off the Board, she would like to discuss a continued role for the Communications Subcommittee. She asked that this be included as a topic at the May meeting.

Dr. Farland commented that there may be a role for the BOSC in reviewing the draft risk assessment staff paper. Communication could be one of the issues to address. He indicated that the staff paper will be available in 2 months. Dr. Schnoor stated that some Board members are interested in reviewing the risk assessment paradigm. To facilitate discussions of future BOSC business at he May meeting, Dr. Johnson asked several Board members (specified below) to develop a 1-page summary on each of the following topics:

- ✧ BOSC workshop on risk assessment—Dr. Henderson
- ✧ Public health outcomes—Dr. Daston
- ✧ Interagency relationships—Dr. Lambert
- ✧ Homeland security—Dr. Farland

Dr. Schnoor noted that much of the May meeting agenda will be filled with reports from the MYP Subcommittees.

Dr. Johnson asked members to check their calendars for September 16-17, 2004, or September 23-24, 2004, so that he can schedule the fall meeting. Ms. Kowalski agreed to poll the members about their availability for the September meeting. Dr. Schnoor asked for a motion to adjourn the meeting. Dr. Daston moved to adjourn, and Dr. Bostrom seconded the motion. The meeting was adjourned at 1:30 p.m.

Action Items

- ✧ BOSC members will send via e-mail nominations with expertise in behavioral science and air pollution to Lori Kowalski. Curricula vitae (CV) should be attached to the nominations.

- ✧ Dr. Gilman will share the results of the state of staff paper review with the BOSC in the next few months.

- ✧ Ms. Kowalski will determine if it is possible and what must be done to include government employees on the Subcommittees. She will inform the Board once she obtains the information.

- ✧ The BOSC members should encourage qualified candidates to apply for the nine vacant NPD positions.

- ✧ Dr. Schnoor asked Drs. Bostrom, Johnson, and Henderson to work together to reword the charges and to make them more parallel. This task was completed before the meeting adjourned. The revised questions are listed on page 25 of this summary.

- ✧ Dr. Schnoor asked the BOSC members to provide names of appropriate experts to the Subcommittee Chairs by January 30.

- ✧ Dr. Lambert agreed to provide an update on SAB activities at the May BOSC meeting.

- ✧ Dr. Farland agreed to provide an update at the May meeting on ORD's efforts to fill the nine National Program Director positions. Specifically, he will notify the BOSC about the number of applications received for the positions.

- ✧ Dr. Farland and Ms. Kowalski will investigate the possibility of including the BOSC members on a listserv similar to that used to keep SAB members informed of EPA activities and announcements.

- ✧ Dr. Scheraga agreed to provide copies of the WHO publication "Climate Change and Human Health—Risks and Responses" to Ms. Kowalski for distribution to the BOSC members.

- ✧ Dr. Schnoor asked the Subcommittee Chairs to develop and submit their lists of self-study questions to Ms. Kowalski quickly, as well as requests for materials to review and a list of individuals to be interviewed.

- ✧ Dr. Schnoor asked the Subcommittee Chairs to submit their lists of names for potential Subcommittee members to Ms. Kowalski as soon as possible. He also asked them to give some thought to the locations for the site visits and the possible dates. In addition, the Chairs should provide Ms. Kowalski with an estimate of person days required for the review.

- ✧ Dr. Daston will prepare a charge for the Computational Toxicology Subcommittee that will lay out the parameters for advising ORD on the research strategy.

- ✧ Dr. Farland will discuss with Tim Oppelt what homeland security products may be ready for review in fall 2004, and report Mr. Oppelt's answer at the May meeting.

- ✧ Ms. Kowalski will contact each of the Laboratory/Center Directors and ask them to submit their comments on the Communications Subcommittee Report by January 30. Ms. Kowalski will provide

the comments to Dr. Bostrom so that she can determine what changes, if any, should be made to the report.

- ✧ Dr. Bostrom asked that a discussion of the continued role for the Communications Subcommittee be added to the agenda for the May meeting.

- ✧ Dr. Henderson will prepare a one-page summary on the possibility of conducting a BOSC risk assessment workshop for discussion at the May meeting.

- ✧ Dr. Daston will prepare a one-page summary on what the BOSC might do with regard to public health outcomes for discussion at the May meeting.

- ✧ Dr. Lambert will prepare a one-page summary on what the BOSC might do to improve interagency relationships for discussion at the May meeting.

- ✧ Dr. Farland will prepare a one-page summary on what the BOSC might do with regard to homeland security for discussion at the May meeting.

- ✧ Ms. Kowalski agreed to poll the BOSC members about their availability for a meeting September 16-17, 2004, or September 23-24, 2004, so that she can set the date for the fall meeting.

Board of Scientific Counselors Executive Committee

Chair:

Jerald L. Schnoor, Ph.D.
Professor, Department of Civil
& Environmental Engineering
The University of Iowa
4112 Seaman's Center (SC)
Iowa City, IA 52242
Phone: 319-335-5649
Fax: 319-335-5660
E-mail: jerald-schnoor@uiowa.edu

Vice-Chair:

James H. Johnson, Jr., Ph.D.
Dean, College of Engineering, Architecture,
and Computer Sciences
Howard University
2366 Sixth Street, NW, Room 100
Washington, DC 20059
Phone: 202-806-6565
Fax: 202-462-1810
E-mail: jj@scs.howard.edu

Members:

Daniel Acosta, Jr., Ph.D.
Dean, College of Pharmacy
University of Cincinnati
3223 Eden Avenue
Room 136HPB
Cincinnati, OH 45267-0004
Phone: 513-558-3326
Fax: 513-558-4372
E-mail: daniel.acosta@uc.edu

Ann Bostrom, Ph.D.
Associate Professor
Georgia Institute of Technology
School of Public Policy
685 Cherry Street
Atlanta, GA 30332-0345
Phone: 404-894-3196 (receptionist)
Fax: 404-894-0535
E-mail: ann.bostrom@pubpolicy.gatech.edu

James R. Clark, Ph.D.
Exxon Mobil Research & Engineering Co.
3225 Gallows Road, Room 3A412
Fairfax, VA 22037
Phone: 703-846-3565
Fax: 703-846-6001
E-mail: jim.r.clark@exxonmobil.com

Michael T. Clegg, Ph.D.
Distinguished Professor of Genetics
Department of Botany & Plant Sciences
University of California
900 University Avenue
2132 Bachelor Hall
Riverside, CA 92521
Phone: 909-787-4672
Fax: 909-787-4437
E-mail: michael.clegg@ucr.edu

George P. Daston, Ph.D.
Miami Valley Laboratories
The Proctor & Gamble Company
11810 E. Miami River Road
Cincinnati, OH 45252
Phone: 513-627-2886
Fax: 513-627-0323
E-mail: daston.gp@pg.com

Elaine J. Dorward-King, Ph.D.
Head of Health, Safety, and Environment
Rio Tinto plc
6 St. James's Square
London SW1Y 4LD
United Kingdom
Phone: +44 20 7753 2183
Fax: +44 20 7753 2413
E-mail: elaine.dorward-king@riotinto.com
-or-
3006 Creek Road
Park City, UT 84098

Board of Scientific Counselors Executive Committee (Continued)

Anna K. Harding, Ph.D., R.S.
Associate Professor
Department of Public Health
309 Waldo Hall
Oregon State University
Corvallis, OR 97331-6406
Phone: 541-737-3830
Fax: 541-737-4001
E-mail: Anna.Harding@oregonstate.edu

Rogene F. Henderson, Ph.D., DABT
Deputy Director
National Environmental Respiratory Center
Lovelace Respiratory Research Institute
2425 Ridgecrest Drive, S.E.
Albuquerque, NM 87108
Phone: 505-348-9464
Fax: 505-348-4983
E-mail: rhenders@lrri.org

Juarine Stewart, Ph.D.
Professor
Department of Biological Sciences
Clark Atlanta University
223 James P. Brawley Drive, SW
Atlanta, GA 30314
Phone: 404-880-6764
Fax: 404-880-6756
E-mail: jstewart@cau.edu

Herbert L. Windom, Ph.D.
Professor Emeritus
Skidaway Institute of Oceanography
10 Ocean Science Circle
Savannah, GA 31411
Phone: 912-598-2490
Fax: 912-598-2310
E-mail: herb@skio.peachnet.edu

SAB Liaison to BOSC:

George Lambert, M.D.
Associate Professor and Center Director
Center for Child and Reproductive
Environmental Health
Robert Wood Johnson Medical School
University of Medicine and Dentistry
of New Jersey
Piscataway, NJ 08854
Phone: 800-644-0088
Fax: 732-253-3520
E-mail: glambert@umdnj.edu

Committee Staff:

William Farland, Ph.D.
ORD BOSC Liaison
Deputy Assistant Administrator for Science
U.S. Environmental Protection Agency
Office of Research and Development
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-6620
E-mail: farland.william@epa.gov

Lorelei Kowalski
Designated Federal Officer
U.S. Environmental Protection Agency
Office of Research and Development
Office of Science Policy
Ariel Rios Building, 8104R
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-3408
Fax: 202-565-2916
E-mail: kowalski.lorelei@epa.gov

Board of Scientific Counselors Executive Committee (Continued)

Sam Williams
Alternate Designated Federal Officer
U.S. Environmental Protection Agency
Office of Research and Development
Office of Science Policy
Ariel Rios Building, 8104R
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-6782
Fax: 202-565-2916
E-mail: williams.sam@epa.gov

Additional Meeting Participants

James Avery
U.S. Environmental Protection Agency
Office of Research and Development
Office of Science Policy
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-6768
E-mail: avery.james@epa.gov

Beverly Campbell
The Scientific Consulting Group, Inc.
656 Quince Orchard Road, Suite 210
Gaithersburg, MD 20878
Phone: 301-670-4990
Fax: 301-670-3815
E-mail: bcampbell@scgcorp.com

Dick David
U.S. Environmental Protection Agency
Office of Research and Development
IOAA
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-3376
E-mail: david.richard@epa.gov

Elaine Francis, Ph.D.
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Research
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-6789
E-mail: francis.elaine@epa.gov

Janet Gamble
U.S. Environmental Protection Agency
National Center for Environmental Assessment
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-3387
E-mail: gamble.janet@epa.gov

Paul Gilman, Ph.D.
U.S. Environmental Protection Agency
EPA Science Advisor and Assistant Administrator
Office of Research and Development
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-6620
E-mail: gilman.paul@epa.gov

Robert Kavlock, Ph.D.
U.S. Environmental Protection Agency
Office of Research and Development
National Health and Environmental Effects Research Laboratory
Research Triangle Park, NC 27711
Phone: 919-541-2771
E-mail: kavlock.robert@epa.gov

Gary Kayajanian
Consultant
Phone: 703-920-0623

Curtis Kimbel
U.S. Navy

John Miller
U.S. Environmental Protection Agency
Office of Research and Development
Office of Science Policy
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-1564
E-mail: miller.johne@epa.gov

Peter W. Preuss, Ph.D.
U.S. Environmental Protection Agency
Office of Research and Development
Director
National Center for Environmental Assessment
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-3322
E-mail: preuss.peter@epa.gov

Additional Meeting Participants (Continued)

Lawrence Reiter, Ph.D.
U.S. Environmental Protection Agency
Office of Research and Development
Director
National Health and Environmental Effects Research Laboratory
Office of Research and Development (MD-51)
Research Triangle Park, NC 27711
Phone: 919-541-2281
E-mail: reiter.larry@epa.gov

Joel Scheraga, Ph.D.
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-3385
E-mail: scheraga.joel@epa.gov

Neil Shah
Inside Washington Publishers

Subhas Sikdar, Ph.D.
U.S. Environmental Protection Agency
Office of Research and Development
National Risk Management Research Laboratory
26 West Martin Luther King Drive
Mail Stop 497
Cincinnati, OH 45268
Phone: 513-569-7528
E-mail: sikdar.subhas@epa.gov

Mike Slimak, Ph.D.
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-3324
E-mail: slimak.michael@epa.gov

Bill Stelz
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Research
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-6834
E-mail: stelz.william@epa.gov

Kevin Teichman, Ph.D.
U.S. Environmental Protection Agency
Office of Research and Development
Director
Office of Science Policy
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-6705
E-mail: teichman.kevin@epa.gov

Vivian Turner
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Research
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-6793
E-mail: turner.vivian@epa.gov

Vanessa Vu, Ph.D.
U.S. Environmental Protection Agency
Director, SAB Staff Office
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 202-564-4533
E-mail: vu.vanessa@epa.gov

Susie Warner
The Scientific Consulting Group, Inc.
656 Quince Orchard Road, Suite 210
Gaithersburg, MD 20878
Phone: 301-670-4990
Fax: 301-670-3815
E-mail: swarner@scgcorp.com

Additional Meeting Participants (Continued)

Paul Zielinski
U.S. Environmental Protection Agency
Office of Research and Development
Office of Science Policy
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460
E-mail: zielinski.paul@epa.gov

Harold Zenick, Ph.D.
U.S. Environmental Protection Agency
Office of Research and Development
National Health and Environmental Effects
Research Laboratory
Mail Stop 105-01
Research Triangle Park, NC 27711
Phone: 919-541-2283
E-mail: zenick.hal@epa.gov